Veterinary Services Proposed Framework
for Response to Emerging Animal Diseases
In the United States

Introduction

Veterinary Services (VS) proposes a framework to help it respond effectively to emerging diseases. This framework will help VS identify and evaluate emerging disease events and define the appropriate responses. VS plans to work with all relevant stakeholders in implementing the appropriate responses. This framework document defines the process by which VS will identify, evaluate, and respond to emerging diseases, and the implementation of this process as a VS core business practice.

Emerging animal diseases include occurrences of illness or death in animals caused by a newly identified pathogen or strain, a known pathogen in a new geographic location, or a new presentation of a known pathogen. These disease events may negatively affect animal health, public health, and trade. Examples of such disease occurrences in the United States in the past 20 years include porcine reproductive and respiratory syndrome, infectious salmon anemia, West Nile virus, and monkey pox virus. More recent examples include the emergence of Schmallenberg virus in Europe and porcine epidemic diarrhea virus in the United States. (See Appendix 1 for a further definition of an emerging animal disease.)

VS has long engaged in emerging disease detection and response. Since 2001, VS strategic plans have incorporated identification and response to emerging diseases within their major goals. The "VS: A New Perspective" document also includes the concepts of identification, analysis, and response to emerging diseases.

Rapid detection and response to emerging diseases are critical to animal agriculture. Some emerging diseases can spread rapidly, threatening the livelihood of producers and limiting their access to important export markets. Rapid response to emerging diseases can prevent or limit sudden and negative animal health, economic, food security, and public health consequences by providing useful animal health information to cooperators and Agency policymakers to inform their actions.

VS has an extensive capacity and history of working with animal agriculture participants, academic institutions, and State animal health officials. VS intends to apply this collaborative approach and our expertise to increase awareness of, detect and identify, characterize, investigate, and respond to emerging disease threats, and provide accurate information to all interested parties. VS will use the activities

> Rapid detection and response to emerging diseases is a VS core business practice.

identified in this framework to provide a solid scientific foundation for developing strategic intervention actions and informing the public of all appropriate actions. These may or may not require a regulatory response.

Approach

This document describes four goals for addressing emerging diseases:
1) Undertake global awareness, assessment, and preparedness for animal diseases or pathogens not currently in the United States that may be of animal or public health concern or have trade implications;
2) Detect, identify, and characterize disease events;
3) Communicate findings and inform stakeholders; and
4) Respond quickly to minimize the impact of disease events.

A fifth goal, addressing recovery from the event, would include strategies that stabilize animal agriculture, the food supply, and the economy, and protect public health and the environment. These activities are an extension of this framework and will not be detailed here. They include the secure food supply initiatives (Secure Pork Supply Plan, etc.; see the VS Web site for more details).

Goal 1: Global awareness, assessment, and preparedness

VS recognizes the need to have an enhanced system for detecting emerging diseases in the United States and in other countries. The Risk Identification Unit (RIU) within the Center for Epidemiology and Animal Health (CEAH) is primarily responsible for identifying emerging diseases globally, including those that may pose a threat to U.S. agriculture. The group will work with other areas in VS and the Animal and Plant Health Inspection Service (APHIS), other government and Tribal agencies, industry, and other stakeholders to identify and describe emerging animal diseases.

International emerging diseases will be identified and characterized, in part from contacts established through APHIS International Services and regional and global partners such as the Inter-American Institute for Cooperation on Agriculture, the International Regional Organization for Plant and Animal Health, the Pan-American Foot and Mouth Disease Centre, the World Organization for Animal Health (OIE), the Food and Agriculture Organization of the United Nations, and the World Health Organization.

Domestically, the RIU will use information resources established as part of VS' nationwide Federal system of animal health professionals. This system has direct contact with accredited veterinarians; producers; livestock market operations; diagnostic laboratories; universities; State

> VS will evaluate and monitor global emerging diseases and develop science-based options for response.

and Tribal animal health, public health, and wildlife health officials; and other Federal agencies, such as the Food and Drug Administration, the Centers for Disease Control and Prevention (CDC), the Environmental Protection Agency, the U.S. Department of the Interior, the U.S. Department of Homeland Security (DHS), and the U.S. Department of Defense. These activities will allow VS to provide a broad scope of information to stakeholders, decisionmakers, and incident responders by incorporating both international and domestic perspectives.

A cross-unit VS team led by the RIU will evaluate global emerging animal diseases, recommend priority status for a disease, and present alternative actions for VS. VS' Science, Technology, and Analysis Services division will assess pertinent issues and develop science-based options for response. In addition, regular meetings or conference calls will be held with stakeholders to gather additional input and to prioritize areas to address.

Goal 2: Detect, Identify, and Characterize

A variety of sources or systems can help detect an emerging animal disease in the United States. These include producers, practitioners, diagnostic laboratories, researchers, internet sources, public health information sources, State and Federal field forces, and active and passive ongoing surveillance and monitoring programs. Consequently, strong partnerships and constant communication among these partners will promote early awareness that an emerging animal disease may exist. Enhanced passive surveillance (EPS) provides a framework for reporting disease events that meet syndromic case definitions or observations without a specific disease diagnosis. An emerging animal disease is likely to present itself in this way. VS is currently collaborating with DHS and other stakeholders on the development of a system for reporting such events through EPS.

> VS will employ passive and active systems to detect emerging diseases, including mandatory reporting.

Once there is a case definition for reporting purposes, an emerging disease must be rapidly reported if VS and our stakeholders are to consider early intervention actions before the event is amplified. VS, the U.S. Animal Health Association (USAHA), and the American Association of Veterinary Laboratory Diagnosticians (AAVLD) have developed a nationally consistent approach for reporting animal diseases – the National List of Reportable Animal Diseases (NLRAD). VS intends to promulgate regulations which will require that diseases on this list, as well as any newly emerging disease, be reportable to VS as the national veterinary authority.

Through this VS-USAHA-AAVLD collaboration, standard operating procedures have been drafted to approve and maintain the NLRAD. Once VS implements the list and finalizes the reporting parameters, it will consider updates and edits to the NLRAD when amending its

3

regulations and guidance documents or the National Veterinary Stockpile list. Updates will also be considered when changes are made to the U.S. Department of Health and Human Services-U.S. Department of Agriculture Select Agent List, the CDC bioterrorism agent list, or the OIE list of reportable diseases; when an emerging issue or condition develops that may require addition to the NLRAD; and on stakeholder request.

Once initial detections of disease are identified and reported, either through confirmed laboratory diagnostics or significant morbidity or mortality events without diagnostic confirmation, VS will launch an investigation. VS Guidance Document 12001.2, *Policy For the Investigation of Potential Foreign Animal Disease/Emerging Disease Incidents,* provides VS personnel, State and Tribal animal health officials, and National Animal Health Laboratory Network laboratories specific guidance for conducting investigations and reporting results for emerging animal disease events.

The primary reason for conducting field investigations will be to quickly learn about the source and circumstances that led to the emerging disease. The findings of the investigation will allow VS and our stakeholders to make science-based decisions on how to reduce disease spread, either in animals or, in the case of zoonotic diseases, in humans.

A top priority in addressing an emerging disease is to gather information on key considerations to determine the best options for engagement. These considerations include, but are not limited to, the following:
- Trade impacts (interstate and international);
- Food security impacts (real vs. perceived, transmission via meat products);
- Public health impacts (real vs. perceived);
- Animal health impacts (morbidity, mortality, incidence, clinical signs, species affected, apparent mode of transmission);
- Production impacts (including segment of industry affected);
- Environmental impacts (wildlife susceptibility, disposal issues);
- Geographic scope (local, regional, national, or international, extent and rate of spread);
- Politics;
- Resource intensity;
- Available expertise;
- Diagnostic capabilities (validity of diagnosis, availability of laboratory tests, sensitivity and specificity of diagnostic tests);
- Authorities; and
- Potential for bioterrorism.

> VS will collaborate with stakeholders to rapidly investigate and assess emerging diseases.

VS will discuss this information with State and Tribal animal health officials and industry representatives to aid all parties in determining the appropriate level of engagement.

Goal 3: Communicate findings and inform stakeholders

As the Federal Agency responsible for safeguarding animal health, VS must both receive and disseminate, in a nationally coordinated fashion, information about emerging disease events. Throughout and following the initial detection, identification, and characterization phase, VS must serve as the nationally recognized source for official information and must be in regular communication with all relevant stakeholders. The affected industry, States, other Federal Agencies, international trade partners, Congress, and the public expect VS to have consistent, complete, and correct information about an emerging animal disease event. As an event progresses, VS will need to continuously gather and disseminate information.

Data and reporting. During the initial response, VS must collect, analyze, and summarize data on cases by time, place, and host characteristics to suggest a source of the outbreak, type of spread (common source or propagative), and method of transmission. Generating hypotheses is critical, and during later response phases, epidemiological field studies (e.g., case-control; retrospective cohort) should be conducted to test the hypotheses. This analytical epidemiology wave is needed to characterize the magnitude and scope of the problem, and the information can be used to formulate an immediate response. Flexible and available information technology systems are essential to support this analysis and reporting.

VS may develop and share other data, including investigation reports, educational materials, pathway analyses, and predictive modeling. Most importantly, VS should quickly and clearly communicate the actions it will take to answer questions about the threat and impact of the disease, fully characterize the event (past, present, and future), and gather and use information to develop policy if that becomes necessary.

Data security is a critical aspect of information management during an emerging disease event. VS will store, handle, and analyze data within secure Federal information technology systems. Where appropriate, VS will collaborate with States, Tribes, and third-parties to access and analyze data. VS will only publish analyses and reports that contain aggregated data and do not specifically identify producers or individual facilities.

> While maintaining appropriate data security, VS will serve as the national repository for shared information on emerging disease events.

5

Goal 4: Respond to minimize impacts

The response to an emerging disease will likely be different from a foreign animal disease response. The response to a recognized foreign animal disease (e.g., highly pathogenic avian influenza) is well defined and often immediately requires aggressive measures, including depopulation. In these cases, the causative agent is often well known and the disease and its effects are well understood, as are the measures needed to deal with the disease. These have been examined thoroughly.

For emerging diseases, VS will undertake adaptive response measures, rather than a predetermined control action. Unknowns may limit the agency response to understanding the epidemiology and ecology of the disease and pathogen using all available resources, and then to rapidly share accurate information and intervention options with stakeholders. If control or eradication measures are recommended, VS will provide science- and risk-based approaches and systems to facilitate industry continuity of business operations, limit spread of the disease, and prescribe coordinated approaches for eliminating the disease from populations of animals. If control or eradication measures include hold orders or depopulation, VS will work with industries, States, and Tribes to identify appropriate compensation mechanisms.

Assessing response options. With accurate, consistent, and shared information comes the ability to collaborate on appropriate responses. These responses range from information dissemination to full mobilization of resources for rapid eradication. VS will work with the affected industry, States, and other affected stakeholders to determine and implement the appropriate response.

VS may form State-industry-Federal working groups, deploy rapid response assessment teams, or use the National Incident Management System and incident management teams. Other VS actions may include diagnostics and vaccine development, education, implementation of certification programs, control measures such as vaccination and movement restrictions, and identification of research priorities. VS will assume a leadership role when providing services (e.g., information sharing) to a primary responder; when partnering with industry, States, and Tribes (e.g., epidemiology investigations; surveillance); or when coordinating a response (e.g., coordination of quarantine and depopulation actions; indemnification). VS may also support stakeholder actions by providing human resources, funding, technical expertise, and educational and outreach materials.

Two tools may be used to assess response options. VS is increasingly using TAIO (Technique for the Assessment of Intervention Options), an approach that can engage internal and external stakeholders, reduce complexity, and ensure transparency in evaluating disease

> "Response" to emerging diseases does not always necessitate depopulation.

> VS will lead the collaborative development and implementation of emerging disease response options.

6

management, surveillance, or response actions. The outcome of TAIO is an assessment of the epidemiological and economic success of selected options. See Appendix 2 for more information on the TAIO process.

Decision Lens is a program that facilitates prioritization and resource allocation that best matches overall strategies. It can combine data inputs and other intelligence to evaluate and support decisions.

Preparedness. An effective collaborative response to an emerging disease requires advance preparation. Preparedness and response planning for emerging disease incidents are crucial to effectively protect public health, animal health, animal agriculture, the food supply, and the economy. VS and our stakeholders—local, State, Tribal, and Federal government agencies, and food and agriculture industries—must collaborate to develop coordinated incident goals, guidelines, strategies, and procedures before an incident.

For any response to an emerging disease, all parties must clearly communicate their goals for managing response efforts. States, Tribes, and industry need a range of options for different situations, and these options must include exercising hold orders or quarantines by State and Tribal animal health officials. Since the industries are affected greatly by any response, industries should develop response strategies for known trans-boundary agents and for situations involving novel agents. Communication and collaboration ahead of an outbreak will reduce the likelihood of unmet expectations, and improve the speed and effectiveness of the response.

Appendix 1: Definition of Emerging Animal Disease

VS defines an emerging animal disease as:
- Any animal disease or infection not known to exist in the United States, including a new strain of a known disease occurring in any animal species, including wildlife;
- An emerging animal disease with zoonotic potential;
- Unexpected and unexplained increase in morbidity or mortality of diseased animals; and
- Evidence of a change in the epidemiology of a known animal disease such as increased pathogenicity, expanded host range, or clinical signs that do not fit the classical picture.

While not diseases, exotic vectors, if identified, should be reported to State and Federal animal health officials for further investigation.

Appendix 2: The TAIO Process

The TAIO process is distinct from other processes used within VS to evaluate potential and existing disease events. A few of the key differences that distinguish the TAIO process from these other analytical processes are:

- The TAIO process integrates economic (benefit-cost), risk assessment, and epidemiological methods into an analysis of disease management intervention options.
- The TAIO process conforms to regulatory requirements for benefit-cost analysis by appropriately framing the objectives of the analysis, establishing explicit performance metrics for the options being assessed, assessing each option in terms of the level of net benefit produced, and expressing the output of the assessment in terms of risk-weighted benefits and costs. The net benefits measured in the assessment are weighted by the likelihood of success of a given disease intervention option in accomplishing its stated objectives.
- The TAIO process provides an explicit evaluation of the proposed intervention options, concluding with a documented explanation as to why the preferred option is being recommended.
- TAIO reduces decisionmaking complexity through a series of organizational questions that eliminate sectors (e.g., species, commodity, region, time) and pathways that are not directly relevant to the determined objectives.
- Throughout the TAIO process, the state of available data is documented and data gaps are identified. The analysis and recommendations are revised as new information becomes available to fill existing gaps.